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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/674,090

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Yoav Eichen

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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,090

Applicant(s)

EICHEN ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,18-29,31,33,35-39,41,43-45 and 47-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,18-29,31,33,35-39,41,43-45 and 47-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The present Office Action is responsive to the Amendment received on January 12, 2006.

Preliminary Remark

Claims 2, 10-17, 30, 32, 34, 40, 42, and 46 are canceled.

Claims 47-54 are new.

Claim interpretation

For the purpose of examination, the term, "target," has been assumed to be limited to biological molecules; and the term, "recognition moiety," has been also assumed to be limited to biological molecules, as when the claims are read in light of the specification, the terms are limited to the invention which pertains to biological molecules (i.e., nucleic acids, protein, antibody, etc.).

MPEP 608.01(o) states that the meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import.

This is necessary in order to insure certainty in construing the claims in the light of the specification, Ex parte Kotler, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901).

With regard to claim 21, the claim is drawn to a product, and the limitation imposed by claim 21 which recites an intended use, absent any physical recitation of the product that results in the intended use, does not confer any patentable weight.

Claim Objections

The objection of claim 46 under 37 CFR 1.75(c), for being an improper dependent form for failing to further limit the subject matter of a previous claim, made in the Office Action mailed on

Art Unit: 1637

July 13, 2005 is withdrawn in view of the Amendment received on January 12, 2006, canceling the claim.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 3-9, 18-23, 31, 33, 35-38, 43, 44, and 46 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on July 13, 2005 is withdrawn in view of the Amendment received on January 12, 2006 and in careful reconsideration of the application. The rejection of claim 46 is withdrawn in view of its cancellation.

The new matter rejection of claims 10, 12, 13, 15, 16, and 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, made in the Office Action mailed on July 13, 2005 is withdrawn in view of the Amendment received on January 12, 2006, canceling the rejected claims.

The rejection of claims 30, 40 and 42 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, made in the Office Action mailed on July 13, 2005 is withdrawn in view of the Amendment received on January 12, 2006, canceling the rejected claims.

Rejection, New Ground – Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9, 18-23, 31, 33, 35-38, 41, 43, 44, and 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1637

Claim 1 is indefinite for reciting the phrase, "binding to said target if said target is present," because the claim has been amended to become drawn to employing a recognition moiety which bind to a component of a target. Therefore, the while the target (which is virus, cell, or bacterium) could be present, the recognition moiety binds to a component therefrom and not the target.

Claims 3-9, 18-23, 38, 43, and 44 are indefinite by way of their dependency on claim 1.

Claim 19 is indefinite for reciting the phrase, "all assay sets of electrodes are for assaying the same target," because it is unclear whether different components of the same target (e.g., different nucleic acids (or components) of a single cell target) are being assayed or same components of the same target is being assayed.

Claims 31, 35, and 37 are indefinite for the same reasons as set forth in the rejection of claim 1.

Claims 33 and 52 are indefinite by way of their dependency on claim 31.

Claims 36, 41, and 53 are indefinite by way of their dependency on claim 35.

Claim 54 is indefinite by way of its dependency on claim 37.

Claim Rejections - 35 USC § 102 - Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 3-5, 24-29, 35, 36, 39, 41, and 43-45 under 35 U.S.C. 102(b) as being anticipated by Braun et al. (Nature February 19, 1998, vol. 391, pages 775-778), made in the Office Action mailed on July 13, 2005 is maintained for the reasons of record.

In addition, the rejection of claims 47-51 and 53 are included herein, as being necessitated by Amendment (by way of their addition).

Applicants' arguments presented in the Amendment received on January 12, 2006 have been fully considered but they are not found persuasive.

Applicants' arguments are addressed in the same order they were presented in the, "Response to Arguments," section.

The Rejection:

Braun et al. disclose a system/device and a method of their use comprising:

(a) an assay device comprising one or more assay sets, each of the assay sets comprising at least two electrodes and a recognition moiety, said recognition moiety being oligonucleotides (page 777, 2nd column, 2nd paragraph);

(b) an electric or electronic module arranged and configured to measure electric conductance;

(c) reagents comprising nucleation-forming entities and combination of metal ions, which detects target DNAs (column 777, 2nd column, *Silver deposition*);

(Figure 1; Figure 4; page 775, 2nd column, 2nd paragraph; page 776, 1st column, 3rd paragraph), anticipating claims 1, 3-5, 24-25, 29, 35, 39, 41, 43, 44, and 45.

With regard to claim 36, Braun et al. disclose that the distance between the electrodes are between 12-16 μm .

Braun et al. disclose that the use of DNA polyanions as a template to fabricate a poly-(*p*-phenylene vinylene) (PPV) filament by attaching a positively charged *pre*-PPV polymer to be stretched DNA and subsequently treating it to form a highly photoluminescent PPV wire known (page 777, 1st column, 2nd full paragraph), anticipating claims 26, 27, and 28.

Art Unit: 1637

With regard to claims 47, 48, and 53, the recognition moiety is oligonucleotides (page 777, 2nd column, 2nd paragraph).

With regard to claims 49-51, the DNA being hybridized to is λ DNA (see page 777, 2nd column, 3rd paragraph, *Constructing the DNA bridge* section).

Therefore, Braun et al. anticipate the invention as claimed.

Response to Arguments:

Applicants contend that the claims, as presently amended, are drawn to a system or a device having assay “sets.” (page 13, 4th paragraph, Response).

This argument is not found persuasive because the claims are drawn to a system or device that has “one or more assay sets,” which embraces a system or device that has a single assay set.

Further more, even if, *arguendo*, that the claims do recite multiple assay sets, as far as the system claims are concerned, such would be an obvious modification if one of ordinary skill in the art would be motivated to employ the DNA circuitry of Braun et al. for making multiple circuits.

Applicants also contend that the system or the device, as presently amended, comprises a recognition moiety being capable of binding to a component of a target selected from the group consisting of a bacterium, a virus, and a cell, which is not taught by Braun et al.

This argument is not found persuasive either in view of the fact that the DNA being hybridized to the device of Braun et al. is explicitly disclosed as being λ DNA (see page 777, 2nd column, 3rd paragraph, *Constructing the DNA bridge* section).

It is a well known fact that λ DNA is a DNA isolated from bacteriophage lambda (see any product catalog, such as New England BioLabs® Inc.)

Therefore, the system and the device of Braun et al. do comprise recognition moiety which bind to a component of target, wherein said target is a bacterium.

In addition, with regard to the method claims, the hybridization of the λ DNA to the recognition moieties (or its detection) is inherently revealed with the circuit is completed.

Therefore, the invention as claimed is clearly anticipated by Braun et al.

Claim Rejections - 35 USC § 103

The rejection of claims 34 and 46 under 35 U.S.C. 103(a) as being unpatentable over Braun et al. (Nature February 19, 1998, vol. 391, pages 775-778), made in the Office Action mailed on July 13, 2005 is withdrawn in view of the Amendment received on January 12, 2006, canceling the rejected claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection, Maintained

The rejection of claims 31 and 33 under 35 U.S.C. 103(a) as being unpatentable over Braun et al. (Nature February 19, 1998, vol. 391, pages 775-778), made in the Office Action mailed on July 13, 2005 is maintained for the reasons of record.

In addition, the rejection of claim 52 is included herein as being Necessitated by Amendment (e.g., by its addition).

Applicants' arguments presented in the Amendment received on January 12, 2006 have been fully considered but they are not found persuasive.

Art Unit: 1637

Applicants' arguments are addressed the same order they were presented in the, "Response to Arguments" section.

The Rejection:

Braun et al. disclose a system/device and a method of their use comprising:

(a) an assay device comprising one or more assay sets, each of the assay sets comprising at least two electrodes and a recognition moiety, said recognition moiety being oligonucleotides (page 777, 2nd column, 2nd paragraph);

(b) an electric or electronic module arranged and configured to measure electric conductance;

(c) reagents comprising nucleation-forming entities and combination of metal ions, which detects target DNAs (column 777, 2nd column, *Silver deposition*) (Figure 1; Figure 4; page 775, 2nd column, 2nd paragraph; page 776, 1st column, 3rd paragraph).

Braun et al. disclose that the distance between the electrodes are between 12-16 μm .

Braun et al. disclose that the use of DNA polyanions as a template to fabricate a poly-(*p*-phenylene vinylene) (PPV) filament by attaching a positively charged *pre*-PPV polymer to be stretched DNA and subsequently treating it to form a highly photoluminescent PPV wire known (page 777, 1st column, 2nd full paragraph).

Braun et al. do not explicitly disclose that the device and the reagents employed in their disclosure are packaged as a kit.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the device and the reagents employed by Braun et al. into a kit in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

Art Unit: 1637

With regard to claim 52, the recognition moiety is an oligonucleotide (or nucleic acid; *see* page 777, 2nd column, 2nd paragraph)

Therefore, the invention as claimed is obvious over the cited references.

Response to Arguments:

Applicants contend that the claims, as amended, are not obvious over Braun et al. because the claims have been amended to comprise an assay device having a recognition moiety capable of specific binding to a component of one of the targets selected from the group consisting of a bacterium, a virus, and a cell (page 14, bottom paragraph, Response).

This argument is not found persuasive in view of the fact that the DNA being hybridized to the device of Braun et al. is explicitly disclosed as being λ DNA (see page 777, 2nd column, 3rd paragraph, *Constructing the DNA bridge* section).

It is a well known fact that λ DNA is a DNA isolated from bacteriophage lambda (see any product catalog, such as New England BioLabs® Inc.)

Therefore, the system and the device of Braun et al. do comprise recognition moiety which bind to a component of target, wherein said target is a bacterium.

In addition, with regard to the intended use of the kit, the intended use being, “for use in assaying one or more targets in a sample,” does not confer any patentable weight for the following reasons.

Consider a kit comprising the device of Braun et al., wherein the recognition moieties are oligonucleotides specific to λ DNA.

Now consider claim drawn to a kit comprising the device of Braun et al., wherein the claim recites that the kit is intended for the detection of λ DNA.

Art Unit: 1637

The fact that the claim recites the intended use of the device does not in any way differentiate the claimed kit from the disclosure of Braun et al.

This is precisely what the courts have discussed in *In re Ngai*, 70 USPQ 2d 1862 (CAFC 2004) wherein the court, referencing *In re Gulak*, 703 F.2d 1381 (Fed. Cir. 1983), held that the printed matter (reciting its intended use) in no way depends on the kit, and the kit does not depend on the printed matter expressing that if a patent were to be granted solely on the presence of a different printed instructions, “anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product,” concluding that a known product by simply attaching a set of instructions to that product would not be entitled a new patent.

Therefore, the invention as claimed is *prima facie* over Braun et al. and the rejection is maintained.

The rejection of claims 6-9, 18-21, 37, and 38 under 35 U.S.C. 103(a) as being unpatentable over Braun et al. (Nature February 19, 1998, vol. 391, pages 775-778), made in the Office Action mailed on July 13, 2005 is maintained for the reasons of record.

In addition, the rejection of claim 54 is included herein as being Necessitated by Amendment (e.g., by its addition).

Applicants’ arguments presented in the Amendment received on January 12, 2006 have been fully considered but they are not found persuasive.

Applicants’ arguments are addressed the same order they were presented in the, “Response to Arguments” section.

The Rejection:

Braun et al. disclose a system/device and a method of their use comprising:

Art Unit: 1637

(a) an assay device comprising one or more assay sets, each of the assay sets comprising at least two electrodes and a recognition moiety, said recognition moiety being oligonucleotides (page 777, 2nd column, 2nd paragraph);

(b) an electric or electronic module arranged and configured to measure electric conductance;

(c) reagents comprising nucleation-forming entities and combination of metal ions, which detects target DNAs (column 777, 2nd column, *Silver deposition*) (Figure 1; Figure 4; page 775, 2nd column, 2nd paragraph; page 776, 1st column, 3rd paragraph).

Braun et al. disclose that the distance between the electrodes are between 12-16 μ m.

Braun et al. disclose that the use of DNA polyanions as a template to fabricate a poly-(*p*-phenylene vinylene) (PPV) filament by attaching a positively charged *pre*-PPV polymer to be stretched DNA and subsequently treating it to form a highly photoluminescent PPV wire known (page 777, 1st column, 2nd full paragraph).

The system/device and the method of their use disclosed by Braun et al. are drawn to a single assay set, that is, a system/device/method comprising two electrodes each of which comprise an oligonucleotide immobilized thereto; and the artisans do not explicitly disclose a system/device comprising multiple assay sets.

It would have been *prima facie* obvious to one of ordinary skill in the art to duplicate the assay set of Braun et al. to arrive at the claimed invention of a system/device comprising multiple assay sets and the method of their use for the following reasons.

In *in re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), the court expressed that duplication of parts, in the instant situation, the duplication of the assay set of Braun et al., has no patentable weight unless a new and unexpected result is provided.

Art Unit: 1637

In the instant situation, one of ordinary skill in the art would have clearly expected that the duplication of the assay set of Braun et al. would have resulted in the multiple and simultaneous detection of targets in sample, as devices comprising a plurality of binding sites has been well known and established in the art of biological detection (*i.e.*, Affymetrix®).

With regard to claims 6-9, while Braun et al. are not explicit in employing other well known metal particles which conduct electricity, such as platinum or gold, for the purpose of “metallizing” the bridge formed between the electrodes of Braun et al., one of ordinary skill in the art would have recognized that any well known colloidal metal particles would have produced such “conductive bridge,” which allows the electricity to pass between the electrodes of Braun et al. One of ordinary skill in the art would have had a reasonable expectation of success at such modification given that Braun et al. already disclose that silver, another well known colloidal metal particle have been employed in generating a “conductive bridge.”

With regard to claim 54, the recognition moiety employed by Braun et al. is oligonucleotide (or nucleic acid).

Therefore, the invention as claimed is *prima facie* obvious over Braun et al.

Response to Arguments:

Applicants contend that the claims, as amended, are not obvious over Braun et al. because the claims have been amended to comprise an assay device having a recognition moiety capable of specific binding to a component of one of the targets selected from the group consisting of a bacterium, a virus, and a cell (page 15, 3rd and 4th paragraphs, Response).

This argument is not found persuasive in view of the fact that the DNA being hybridized to the device of Braun et al. is explicitly disclosed as being λ DNA (see page 777, 2nd column, 3rd paragraph, *Constructing the DNA bridge* section).

Art Unit: 1637

It is a well known fact that λ DNA is a DNA isolated from bacteriophage lambda (see any product catalog, such as New England BioLabs® Inc.)

Therefore, the system and the device of Braun et al. do comprise recognition moiety which bind to a component of target, wherein said target is a bacterium.

In addition, with regard to the intended use of the device, the intended use being, "for use in assaying one or more targets in a sample," does not confer any patentable weight for the following reasons.

Consider a device comprising the device of Braun et al., wherein the recognition moieties are oligonucleotides specific to λ DNA.

Now consider claim drawn to a device comprising the device of Braun et al., wherein the claim recites that the device is intended for the detection of λ DNA.

The fact that the claim recites the intended use of the device does not in any way differentiate the claimed device from the disclosure of Braun et al.

Therefore, the invention as claimed is *prima facie* obvious over the cited references and the rejection is maintained.

Double Patenting

The provisional rejection of claims 1, 3-13, 15, 16, 18-23, 31, and 33-38, 43, 44, and 46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 and 19-32 of copending Application No. 09/462,171 (now a U.S. Patent No. 6,946,675) made in the Office Action mailed on July 13, 2005 is withdrawn in view of the Terminal Disclaimer filed in the Amendment received on January 12, 2006.

Conclusion

No claims are allowed.

The invention is drawn to a system which forms a conductive bridge between two electrodes via treating a complex formed therebetween with reagents which allows electricity to flow. The complex is formed between the two electrodes via immobilization of a recognition moiety to one of the electrodes and a target which binds thereto. While the prior art teaches the above method with regard to the recognition and target being nucleic acids, the prior art does not disclose or suggest the treatment of protein-antibody complex with reagents which results in the formation of the "conductive bridge." As there is no reasonable expectation of success at such modification, claims 22 and 23 drawn to this embodiment is determined to be non-obvious over the prior art.

Inquiries

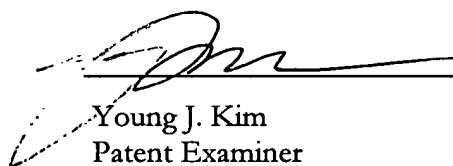
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR

Art Unit: 1637

1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
5/2/2006

**YOUNG J. KIM
PATENT EXAMINER**

yjk